K030967

APR 21 2003

9.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

General Provisions	Trade Name: StarBurst SDE Electrosurgical Device Common/Classification Name: Electrosurgical cutting and coagulation accessory
Name of Predicate	RITA Medical Systems Inc. - Model 90/StarBurst Electrosurgical Device
Classification	Class II
Performance Standards	Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.
Intended Use	The RITA® StarBurst SDE Electrosurgical Device is designed to supply energy (generated by the RITA Medical Systems' electrosurgical generator) for use in electrosurgery and is indicated for use in percutaneous, laparoscopic, or intraoperative coagulation and ablation of soft tissue including: • The partial or complete ablation on non-resectable liver lesions and • The palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy.
Device Description	The RITA StarBurst SDE device is 12-cm in length and can be used for a variety of medical applications. Each secondary electrode deploys out from the side of the trocar through a hole in the wall of the trocar (primary electrode). The RITA device consists of the following components: • *primary electrode*: tubing with a portion exposed as an electrode • *secondary electrodes*: tubing at the distal end of probe • *trocar insulation*: shrink tubing • *handle*: with markings to indicate the amount of secondary electrode deployment from the trocar • *RF pathway*: connection through nine-pin Lemo connector built into the handle • *fluid infusion*: delivery through Luer port at side of the handle • *temperature sensors:* three temperature sensors in the distal section of the secondary electrodes • *depth indicators*: incremental 1 cm marks denote needle penetration depth
Performance Data	The StarBurst SDE devices were subjected to a battery of electrical, mechanical, and functional testing to verify that the devices met the specifications. The devices met the specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 2003

Ms. Erin Mazzone
Director, Quality/Regulatory Affairs
RITA Medical Systems, Inc.
967 N. Shoreline Boulevard
Mountain View, California 94043

Re: K030967
Trade/Device Name: RITA® StarBurst SDE Electrosurgical Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 24, 2003
Received: March 26, 2003

Dear Ms. Mazzone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 INTENDED USE

Indications for Use Statement

510(K) Number (if known): K030967

Device Name: RITA® StarBurst SDE Electrosurgical Device

The RITA® StarBurst SDE Electrosurgical Device is designed to supply energy (generated by the RITA Medical Systems' electrosurgical generator) for use in electrosurgery and is indicated for use in percutaneous, laparoscopic, or intraoperative coagulation and ablation of soft tissue including:

- The partial or complete ablation on non-resectable liver lesions and
- The palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy.

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____

(per 21 CFR 801.109)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices